

Notice of Allowability**Application No.**

09/733,166

Examiner

Bao Qun Li

Applicant(s)

COMPANS ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to June 22, 2004.
2. ☒ The allowed claim(s) is/are 62 and 67.
3. ☒ The drawings filed on 03.12.2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Bao Qun Li

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: Claimed invention is drawn to a method for immunizing a particular population of subject who has a CD4+ T cell deficiency. On the record, the limitation of deficiency in CD4+ T cell is interpreted according to the definition of idiopathic CD4 T lymphocytopenia of US CDC: < 300 CD4+ cells per cubic millimeter or a CD4+cell count < 20 percent of total T cells per cubic milliliter on two occasions (Smith et al. J. New Eng. Med. 1993, Vol. 328, No. 6, pp. 373-379, especially the abstract on page 374) and the standard of CD4+ T cell counts published by ARUP's guide to Clinical laboratory Testing (Lymphocyte Subset Panel 3, T cell-Subsets (CD4 and CD8), absolute Counts only in ARUP's Guide to Clinical laboratory Testing published on 2004).
2. Applicants insist the claimed invention is a surprising and unexpected result by administering an inactivated intact influenza virus to CD4 T cell knock out mice is able to get a full protection against the influenza virus challenge.
3. Applicants states that CD4T helper cells are believed in the state of art, to be essential for induction of a high-affinity antibody response and for efficiency isotype switch from IgM to IgG production (See lines 26-28 on page 2 of specification and lines 18-26 on page 5 of response filed on 06/23/2004 and Fig. 5). Which is true according to the state that teach that the patients who have advanced HIV disease (AIDS or ARC who has very lower CD4+ T lymphocyte cell counts), response to the split or subunit influenza vaccine poorly (Dorrell et al. International Journal of STD & AIDS 1997, Vol. 8, pp. 776-779), and do not induce any protective antibody titers; a second dose of vaccine does not improve the immune response (MMWR 1997, Vol. 46, No. RR-9, pp. 1-25, especially, see page 6).
4. The art teaches that the whole inactivated virus can be used to induce an immune response. However, no prior art teaches or suggests using the inactivated intact virus to immunize patients who has a deficiency in CD4+ T cell. In fact, the state of art teaches that the inactivated whole virus preparation is only recommended to give the person with health condition at above 12 years of age (MMWR 1997, Vol. 46, No. RR-9, pp. 1-25, especially, see page 4).

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5. Therefore, no prior art teaches or suggests immunizing such particular population of human or animal that has deficiency in CD4+ T cell, with an inactivated intact virus.
6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.
8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

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September 02, 2004


JAMES HOUSEL 9/20/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600